

## REMARKS

To the extent that it is not necessary to address particular items within the Office Action in order to provide a complete response, Applicants' choice not to discuss such items is not, and cannot be interpreted as, acquiescence by the Applicants to such items, nor does it or can it be construed to limit the scope of any claims that may eventually issue in this patent application or any patent application claiming priority to this one..

### Election

Applicants confirm the provisional election as set forth in the Office Action.

### Information Disclosure Statement

Applicants have attached page 3 of the form PTO-1449 filed on May 8, 2002 to this paper as Exhibit 1. Page 3 of that form PTO-1449 had been inadvertently omitted.

Applicants filed two boxes of printed references by hand delivery on May 8, 2002, which included the foreign publications cited in the form PTO-1449 filed on May 8, 2002. Attached to this Response to Office Action as Exhibit 2 is the stamped receipt from the Office of Initial Patent Examination (OIPE) and the transmittal letter attached to that receipt, proving submittal of those references to the Patent Office. Applicants request a search of the appropriate storage area or areas to locate those references.

### Drawings

The coil spring is presently shown in the drawings; for example, in schematic in Figures 1 and 4, as callout number 24; the specification states that "[a]dvantageously, the actuator 24 is a coil spring." The presence of callout number 24 in Figures 1 and 4 shows the claimed feature, and thus the drawings satisfy the requirement of 37 CFR 1.83(a). Applicants

have chosen to illustrate this feature schematically, for simplicity, and the schematic illustration of the coil spring shows its external contour and structures to which its ends are connected.

### **35 U.S.C. §112**

Claim 42 has been amended to correct a typographical error in its dependency. Claim 42 now depends from claim 41, as originally intended, and claim 41 includes antecedent basis for the phrase “first driveshaft.”

### **35 U.S.C. §102**

MPEP 2131 quotes Verdegaal Brothers v. Union Oil of California, 814 F.2d 628, 631 (Fed. Cir. 1987) for the legal standard of anticipation: “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” (emphasis added).

### **Claims 1-16**

Applicants respectfully traverse the rejection of these claims.

Claim 1 claims “[a] tool for making an incision in and removing tissue from a vessel wall, comprising: a cutter; and a piercing member positioned within said cutter, wherein said piercing member and said cutter are configured to translate together to penetrate the wall of the vessel.” (emphasis added)

U.S. Pat. No. 5,591,187 to Dekel (“Dekel”) does not expressly or inherently describe each and every element of claim 1. Dekel discloses a “cutting device 12” that “has a central longitudinal passageway 16 formed therein.” (*e.g.*, col. 4, lines 46-56; Figure 1). The “shaft 22 of a T-handled device 18 having a corkscrew-like device 20 at the distal end thereof” is

received in the longitudinal passageway 16 “for slidable and rotatable movement within the passageway 16.” (emphasis added) (col. 4, lines 53-59; Figures 1, 3, 4). The cutting device 12 is itself received in a sheath 10. (e.g., col. 4, lines 33-36; Figure 1). The distal end of the sheath 10 includes serrations 10A that “grip the tissue.” (col. 5, lines 36-39; col. 6, lines 26-27). In operation, “the corkscrew 20 is twisted via the T-handle to engage the tissue sample.” (e.g., col. 6, lines 18-20; col. 5, lines 29-31). Then, “the corkscrew can be retracted by moving it longitudinally toward the operator, thereby to bring [sic] the tissue into engagement with the cutting teeth of the cutting device 12 disposed at the distal open end of the sheath 10.” (emphasis added) (col. 5, lines 30-34). The serrations 10A at the distal end of the sheath 10 then grip the tissue as the cutting device 12 is then rotated to remove the tissue. (col. 5, lines 36-41; col. 6, lines 20-27). Because the corkscrew is moved longitudinally toward the operator to draw tissue into the cutting teeth of the cutting device, it translates relative to the cutting device.

In contrast, the claimed tool comprises “a cutter; and a piercing member positioned within said cutter, wherein said piercing member and said cutter are configured to translate together to penetrate the wall of the vessel.” (emphasis added). The corkscrew and cutting device of Dekel do not and cannot “translate together,” because the corkscrew of Dekel is translated toward the operator during the cutting process. Further, the initial engagement of tissue by the corkscrew results solely from motion of the T-handle connected to the corkscrew, such that the initial engagement of tissue by Dekel also does not involve a corkscrew and cutting device that “translate together.” Thus, Dekel does not disclose a piercing member and a cutter “configured to translate together.”

Further, Dekel admits that the corkscrew is used “[i]f the tissue is a hard specimen.” (col. 6, lines 18-20) If the tissue is soft, tissue is removed using a “feeding window 34” located in the side of the sheath. (col. 5, lines 12-19; col. 6, lines 8-9). Thus, the disclosure of

Dekel with regard to the use of a corkscrew and cutting device to remove tissue is directed to surgical tools for removing hard tissue, not to surgical tools for removing soft tissue such as vascular tissue. Indeed, Dekel expressly teaches away from the use of the disclosed corkscrew and cutting device for cutting soft tissue. (col. 6, lines 8-28). Thus, Dekel neither expressly nor inherently describes each and every element claimed in claim 1, and Applicants believe claim 1 is in condition for allowance.

Claim 1 is generic, so allowance of generic claim 1 would be to all species, including the species of dependent claims 2 and 7, which would therefore be reinstated in this patent application. Claims 2-16 depend directly or indirectly from claim 1, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

With regard to dependent claim 3, the opening 34 of Dekel is simply an opening in the side of the sheath 10. To be “within” an opening, an object has to extend through that opening. Instead, the cutting device 12 does not extend through the opening 34, and is merely positioned in proximity to the opening. Thus, the combination of the opening 34 and the cutting device 12 does not expressly or inherently describe the claimed “cutter; and a piercing member positioned within said cutter.” (emphasis added). Further, Dekel discusses the use of an opening 34 to “macerate” tissue and to remove a “tissue mass.” (col. 6, lines 12-17). Neither of these actions teaches or suggests the use of the opening 34 in the sheath 10 to pierce tissue or to create an opening in tissue of any kind.

With regard to claim 10, Dekel does not expressly or inherently disclose a hemostatic cutter. The term “hemostatic” is related to the flow of blood. Blood, much less blood flow, is not expressly or inherently described in Dekel.

### Claims 17-53

The Examiner objected to claim 19, but indicated that it would be allowable if rewritten in independent form.

During a telephone conference on May 5, the Examiner indicated that claim 17 is generic as to the two species of actuator set forth in claims 18 and 19: the flexible shaft and the coil spring. The coil spring has been elected as the actuator species, and claim 18 stands withdrawn. Thus, the actuator of claim 17 is the coil spring, as elected. As a result, claim 17 effectively includes the subject matter of claim 19, and is believed to be in condition for allowance. As a generic claim, were it to be allowed, it would be allowed as to all species, and Applicants would then request the reinstatement of withdrawn claim 18.

Claims 18-53 depend directly or indirectly from claim 17, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

With respect to claim 30 and the claims that depend therefrom, Dekel discloses a dam 32 that forces tissue bits into a reservoir 30, and a jagged line 8 that simply reveals a cutaway of the device. (col. 4, lines 17-19; col. 5, lines 8-11). Dekel neither expressly nor inherently describes a seal housing or an introducer tip.

### Claims 54-61

Applicants respectfully traverse the rejection of these claims. The discussion above with regard to claim 1 is applicable here.

Claim 54 requires "advancing a piercing member and a cutter through the vessel wall." Dekel does not disclose advancing both a piercing member and a cutter through a vessel wall, or through tissue of any kind. Rather, tissue is moved distally into engagement with the serrations 10A at the distal end of the sheath 10; the sheath 10 is not advanced. (e.g., col. 5, lines 30-38). The "purpose of the serrations 10A is to grip the tissue." (col. 5, lines

37-39). Such serrations 10A at the distal end of the sheath 10 could not grip the tissue of a vessel wall if they were advanced through the vessel wall into an interior of the vessel, because they would be located in a volume of space having no tissue to grip. Second, Dekel does not disclose a method of utilizing a surgical tool for performing any actions on a vessel wall, much less advancing a structure through a vessel wall. Indeed, vessels are notably absent from Dekel.

Claim 54 also requires “retracting said piercing member and said cutter, whereby the cut tissue is removed from the vessel wall to form an opening therein.” In contrast, Dekel does not disclose retracting both a piercing member and a cutter to remove cut tissue from any structure to form an opening therein. Rather, in Dekel, “tissue is then removed by the conveying action of the rotating flutes of the device 12, which acts as a rotary conveyor to convey the tissue along the longitudinal length of the device, whereby it impacts against the dam 32, which causes the tissue then to be diverted into and received in the reservoir 30.” (col. 5, lines 38-43). That is, cut tissue of Dekel is removed by the rotary conveyor action of the cutting device 12 alone. Thus, Dekel fails to teach retracting a piercing member and a cutter, whereby the cut tissue is removed from the vessel wall to form an opening therein. Further, Dekel fails to disclose a vessel, much less the creation of an opening in the wall of a vessel. Thus, Dekel neither expressly nor inherently describes each and every element claimed in claim 54 and Applicants believe claim 54 is in condition for allowance.

Claims 55-61 depend directly or indirectly from claim 54, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

35 U.S.C. §103

MPEP 706.02(j) states:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 1438 (Fed. Cir. 1991) (emphasis added).

Claim 6

Claim 6 depends from claim 1, which is believed to be in condition for allowance, and is thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

Claim 16

Claim 16 depends from claim 1, which is believed to be in condition for allowance, and is thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

Claims 28-29

Claims 28-29 depend from amended claim 17, which is believed to be in condition for allowance, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III). Applicants note that a knob is not equivalent to a handle, and that a knob with a diameter wide enough to provide torque equivalent to the torque produced by the lever arm of the hand crank 14 would have a diameter of twice that lever arm, and would be quite unwieldy, and potentially inoperable, as a result.

#### Claims 52-53

Claims 52-53 depend from amended claim 17, which is believed to be in condition for allowance, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III). Applicants do not acquiesce to the characterization of Dekel as having “an auger of the same structure as the applicant’s.”

#### Claims 55-56, 59

Claims 55-56 and 59 depend from claim 54, which is believed to be in condition for allowance, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

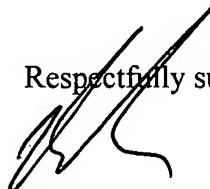
Applicants do not acquiesce to the characterization of claims 55-56 and 59. The use of a hydraulic mechanism is completely independent of whether or not that hydraulic mechanism produces an impulsive force, as the term “impulsive force” is defined in the specification of this patent application. Dekel neither discloses nor suggests anything regarding the duration over which a force is to be exerted. The fact that the preferred embodiment utilizes a hand crank indicates that duration is substantial. Further, Dekel discloses nothing in regard to applying an impulsive force in a “reverse direction.” No part of Dekel is cited as providing support for such characterizations. Gannoe also fails to disclose or suggest the use of an impulsive force.



**REQUEST FOR ALLOWANCE**

Allowance of the pending claims is respectfully solicited. Please contact the undersigned if there are any questions.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Brian A. Schar', written over the closing 'submitted,'.

Brian A. Schar  
Attorney for Applicants  
Reg. No. 45,076  
Tel. No. (650) 331-7162 (direct)  
Chief Patent Counsel  
Cardica, Inc.

## **Exhibit 1**



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Donohoe, Brendan M.  
Assignee: Cardica, Inc.  
Title: Method and Apparatus for Creating an Opening in the Wall of a Tubular Vessel  
Serial No.: 10/054,745 Filing Date: January 22, 2002  
Examiner: Paul A. Roberts Group Art Unit: 3731  
Docket No.: 057

May 11, 2004

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR § 1.97(c)

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In compliance with the Applicant's duty under 37 CFR § 1.56, the information listed on the accompanying form PTO-1449 is brought to the attention of the Examiner. The fee under 37 CFR §1.97(c) is enclosed.

Respectfully submitted,

Brian A. Schar  
Attorney for Applicant(s)  
Reg. No. 45,076  
Cardica, Inc.  
900 Saginaw Drive  
Redwood City, CA 94063

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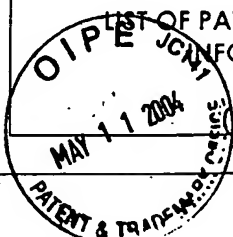
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10/054745


**LIST OF PATENTS AND OTHER ITEMS FOR APPLICANT'S  
INFORMATION DISCLOSURE STATEMENT**

(Use several sheets if necessary)

**APPLICANT:**

Brendan, Donohoe et al.

**FILING DATE:**

1/22/02

**GROUP:**

3731

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE
	5,234,447	8/10/93	KAster, ET AL			
	5,250,058	10/5/93	MILLER, ET AL			
	5,250,060	10/5/93	CARBO, ET AL			
	5,271,544	12/21/93	FOX, ET AL			
	5,275,322	1/4/94	BRINKERHOFF, ET AL			
	5,285,945	2/15/94	BRINKERHOFF, ET AL			
	5,290,298	3/1/94	REBUFFAT, ET AL			
	5,292,053	3/8/94	BILOTTI, ET AL			
	5,304,220	4/19/94	MAGINOT			
	5,314,435	5/24/94	GREEN ET AL			
	5,314,468	5/24/94	MARTINEZ			
	5,324,300	6/28/94	ELIAS ET AL			
	5,333,773	8/2/94	MAIN, ET AL			
	5,336,233	8/9/94	CHEN			
	5,344,059	9/6/94	GREEN ET AL			
	5,350,104	9/27/94	MAIN, ET AL			
	5,354,302	10/11/94	KO			
	5,364,389	11/15/94	ANDERSON			
	5,366,462	11/22/94	KAster, ET AL			
	5,392,979	2/28/95	GREEN ET AL			
	5,395,030	3/7/95	KURAMOTO, ET AL			
	5,395,311	3/7/95	ANDREWS			
	5,403,338	4/4/95	MILO			
	5,423,330	6/13/95	LEE			
	5,443,497	8/22/95	VENBRUX			
	5,447,514	9/5/95	GERRY, ET AL			

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**MAY 17 2004**

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## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION YES NO

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)

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**EXAMINER:****DATE CONSIDERED:**

EXAMINER: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include a copy of this form with next communication to applicant

## **Exhibit 2**

May 1, 2002

Tom Hamill  
National Patent Services  
2101 Crystal Plaza Arcade, Suite 308  
Arlington, Virginia 22207

Re: Applicant(s): Donohoe, Brendan M.; et. al.  
Assignee: Cardica, Inc.  
Title: Method and Apparatus for Creating an Opening in the Wall of a  
Tubular Vessel  
Serial No.: 10/054,745  
Examiner: Not yet assigned  
Docket No.: 057

Filed: January 22, 2002  
Group Art Unit: 3731

Dear Tom:

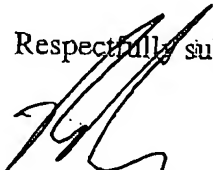
Enclosed are the following documents:

- (1) This letter;
- (2) A Transmittal Letter;
- (3) Information Disclosure Statement Under 37 CFR 1.97(b);
- (4) PTO-1449 (13 pages);
- (5) Return receipt.

Two boxes of references are being transmitted to you via FedEx Ground and hopefully will reach you in a week or so. I will email you the tracking information for these boxes. When you receive them, please hand-deliver them along with the papers in this envelope to the Patent Office. You quoted me a price of \$75 for this service, which will definitely allow me to save some money as compared to Express Mailing these boxes directly to the Patent Office.

Please call me if you have any questions. Thank you.

Respectfully submitted,

  
Brian A. Schar  
Reg. No. 45,076  
Chief Patent Counsel  
Cardica, Inc.  
171 Jefferson Drive  
Menlo Park, CA 94025

**RECEIVED**  
MAY 17 2004  
TECHNOLOGY CENTER R3700



May 1, 2002

Commissioner For Patents  
Washington, D.C. 20231

Re: Applicant(s): Donohoe, Brendan M.; et. al.  
Assignee: Cardica, Inc.  
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Tubular Vessel  
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Examiner: Not yet assigned  
Docket No.: 057

Filed: January 22, 2002  
Group Art Unit: 3731

Dear Sir:

Transmitted herewith are the following documents in the above-identified application:


- (1) This Transmittal Letter;
- (2) Information Disclosure Statement Under 37 CFR 1.97(b);
- (3) PTO-1449 (13 pages);
- (4) Two boxes of references cited in PTO-1449, labeled  
CARDICA Serial No. 10/054,745 Box 1 of 2,  
CARDICA Serial No. 10/054,745 Box 2 of 2; and
- (5) Return receipt.

If an extension of time is required for timely filing of the enclosed documents, an extension of time is hereby requested.

Please charge Deposit Account 502108 for any fees required, and credit deposit account 502108 any amounts overpaid.

**VIA HAND DELIVERY**

Respectfully submitted,

  
Brian A. Schar  
Reg. No. 45,076  
Chief Patent Counsel  
Cardica, Inc.  
171 Jefferson Drive  
Menlo Park, CA 94025

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**MAY 17 2004**  
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ATTY. DOCKET NO.  
057

**SERIAL NO.**  
10/054,745

**APPLICANT:**

Donohoe, Brendan M.; et. al.

**FILING DATE:**

January 22, 2002

**GROUP:**

3731

U.S. PATENT DOCUMENTS

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**EXAMINER:**

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